# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) November 9, 2015

### CARA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation)

001-36279 (Commission File Number) 75-3175693 (IRS Employer Identification No.)

1 Parrott Drive Shelton, Connecticut (Address of principal executive offices)

06484 (Zip Code)

Registrant's telephone number, including area code (203) 567-1500

ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following visions (see General Instruction A.2.):
Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02. Results of Operations and Financial Condition.

Cara Therapeutics, Inc. (the "Company") issued a press release on November 9, 2015 announcing its financial results for the third quarter ended September 30, 2015. A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information furnished pursuant to this Item 2.02 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing. Except as required by law, we undertake no duty or obligation to publicly update or revise the information so furnished.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

No. Description

99.1 Press Release dated November 9, 2015

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CARA THERAPEUTICS, INC.

By: /s/ JOSEF SCHOELL

Josef Schoell Chief Financial Officer (Principal Financial and Accounting Officer)

Date: November 9, 2015



#### Cara Therapeutics Reports Third Quarter 2015 Financial Results

- Initiated Phase 3 program for I.V. CR845 in acute postoperative pain-
  - Initiated Phase 2a trial of Oral CR845 in osteoarthritis patients -
- Earned \$2.75M in milestone payments for clinical development of uremic pruritus -
  - Conference call today at 4:30 p.m. ET -

**SHELTON, CONN., November 9, 2015** – Cara Therapeutics, Inc. (NASDAQ: CARA), a biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors, today announced financial results for the third quarter ended September 30, 2015, and provided a corporate update.

"We continued to make significant progress with our lead development program for I.V. CR845 through the initiation of Cara's first pivotal trial in postoperative pain in September," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We are also pleased to report that our Phase 2a trial of Oral CR845 in osteoarthritis patients is now fully enrolled, and we expect to read out top-line data later this year."

#### Third Quarter and Recent Business/Corporate Highlights

- In September, initiated an adaptive pivotal trial of I.V. CR845 for acute postoperative pain following abdominal surgery.
- In August, initiated a Phase 2a trial of Oral CR845 in OA (osteoarthritis) patients, which completed enrollment in October.
- In July, reported positive top-line results from the Phase 2 trial of I.V. CR845 in moderate to severe uremic pruritus. CR845 achieved statistically significant results on the primary endpoint of reducing worst itch intensity and on the secondary endpoint measuring quality of life improvements.
- In July and September, earned a total of \$2.75 million in milestone payments, before withholding taxes and foreign currency exchange adjustments totaling \$0.4 million, from Maruishi Pharmaceutical Co. Ltd. (Maruishi) and Chong Kun Dang Pharmaceutical Corporation (CKD) in connection with the achievement of three milestone events for the development of CR845: completion of a Phase 1b trial of Oral CR845 and a Phase 2 trial of I.V. CR845 in the U.S. for the treatment of uremic pruritus; and the initiation of a Phase 2 trial of I.V. CR845 in Japan in uremic pruritus.

- In July, completed a public offering of 4,327,956 shares of common stock, including full exercise of underwriters' option to purchase additional shares, at \$18.60 per share, raising approximately \$75.2 million in net proceeds after deducting underwriting discounts and commissions and offering expenses paid or payable by the Company.
- In October, presented two posters at the American Academy of Physical Medicine and Rehabilitation (AAPM&R) Annual Assembly in Boston, which highlighted positive data from Cara's Phase 2 acute pain and human abuse liability studies of I.V. CR845.
- In September, presented a poster at the 8th World Congress on Itch, at the Nara Kasugano International Forum IRAKA in Nara, Japan, titled "Decrease of Itch Intensity by CR845, a Novel Kappa Opioid Receptor Agonist," which discussed the positive data from Cara's Phase 2 study of I.V. CR845 in uremic pruritus.
- In September, sponsored a symposium titled "Kappa Opioid Receptor Agonists (KORAs) Moving Beyond Mu" at PAINWeek 2015.

#### **Expected Upcoming Milestones**

- Report top-line data from Phase 2a trial of Oral CR845 in OA patients in 4Q'15.
- Hold an End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA) to inform the registration program for I.V. CR845 in uremic pruritus in 4Q'15.

#### **Third Quarter 2015 Financial Results**

*Net Loss:* Net loss was \$4.8 million, or \$0.19 per basic and diluted share, for the third quarter of 2015, compared to net loss of \$6.5 million, or \$0.29 per basic and diluted share for the same period of 2014.

*Revenues:* License and milestone fees revenue was \$1.7 million for the third quarter of 2015, related to milestones achieved under the license agreements with CKD and Maruishi, compared to \$0 for the same period of 2014. Collaborative revenue was \$730,000 for the third quarter of 2015, comprising revenue recognized for a portion of the Maruishi milestone payment and revenue that had been deferred upon entry into the Maruishi license agreement, compared to \$1.1 million for the same period of 2014, comprising revenue that had been deferred upon entry into the Maruishi license agreement.

Research and Development (*R&D*) Expenses: R&D expenses were \$5.6 million in the third quarter of 2015, compared to \$6.2 million for the same period of 2014. The lower R&D expenses in the third quarter of 2015 were principally due to a net decrease in direct preclinical studies and clinical trial costs, including consultant services, partially offset by increases in payroll and related costs, including stock option expense, associated with R&D personnel.

*General and Administrative (G&A) Expenses:* G&A expenses were \$1.9 million in the third quarter of 2015, compared to \$1.5 million in the same period of 2014. The increase in the third quarter of 2015 was primarily due to increases in payroll and related costs, including stock option expense, mostly due to increases in headcount.

*Interest Income*: Interest income was \$22,000 for the third quarter of 2015, compared to \$26,000 for the same period of 2014.

Cash Position: At September 30, 2015, cash and cash equivalents were \$111.1 million, compared to \$43.2 million at June 30, 2015. The increase was principally related to the Company's recent public follow-on offering of common stock, which raised approximately \$75.2 million in net proceeds after deducting underwriting discounts and commissions and offering expenses paid or payable by the Company. Those net proceeds were partially offset by cash and cash equivalents used in operating activities during the third quarter of 2015.

#### **Conference Call**

Cara management will host a conference call today at 4:30 p.m. ET to discuss third quarter 2015 financial results and provide a business update.

To participate in the conference call, please dial 855-445-2816 (domestic) or 484-756-4300 (international) and refer to conference ID 67276671. A live webcast of the call can be accessed under "Events and Presentations" in the News & Investors section of the Company's website at <a href="https://www.CaraTherapeutics.com">www.CaraTherapeutics.com</a>.

An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

#### **About Cara Therapeutics**

Cara Therapeutics is a clinical-stage biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors. Cara is developing a novel and proprietary class of product candidates that target the body's peripheral nervous system and have demonstrated efficacy in patients with moderate-to-severe pain without inducing many of the undesirable side effects typically associated with currently available pain therapeutics.

#### **Forward-looking Statements**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning the expected timing for the Company's clinical trials and the reporting of clinical trial results, the potential results of ongoing and planned clinical trials and future regulatory and development milestones for the Company's product candidates, and the timing of the Company's meeting with the FDA to inform the registration program for I.V. CR845 in uremic pruritus. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Cara Therapeutics' filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2014, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Cara Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Financial tables follow

## CARA THERAPEUTICS, INC. CONDENSED BALANCE SHEETS

(in thousands) (unaudited)

	September 30, 2015		Dec	December 31, 2014	
Assets	_		_		
Current assets:					
Cash and cash equivalents	\$	111,116	\$	52,663	
Income tax receivable		450		200	
Other receivables		2,143		_	
Prepaid expenses	_	1,971		287	
Total current assets		115,680		53,150	
Property and equipment, net		1,517		2,084	
Restricted cash	_	700		700	
Total assets	\$	117,897	\$	55,934	
Liabilities and stockholders' equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	3,374	\$	1,946	
Deferred Revenue	_			1,452	
Total current liabilities		3,374		3,398	
Deferred lease obligation		660		874	
Commitments and contingencies		_		_	
Stockholders' equity:					
Preferred stock		_		_	
Common stock		27		23	
Additional paid-in capital		209,197		131,840	
Accumulated deficit	_	(95,361)		(80,201)	
Total stockholders' equity		113,863		51,662	
Total liabilities and stockholders' equity	\$	117,897	\$	55,934	

## CARA THERAPEUTICS, INC. CONDENSED STATEMENTS OF OPERATIONS

(amounts in thousands, except share and per share data) (unaudited)

		Three Months Ended September 30,			Nine Months Ended September 30,				
	_	2015 2014		2015		2014			
Revenue:									
License and milestone fees revenue	\$	1,710	\$	_	\$	1,710	\$	302	
Collaborative revenue		730		1,125		2,093		1,802	
Clinical compound revenue		_		_		_		159	
Total revenue		2,440		1,125		3,803		2,263	
Operating expenses:									
Research and development		5,584		6,208		13,653		11,609	
General and administrative		1,865		1,520		5,609		4,390	
Total operating expenses		7,449		7,728		19,262		15,999	
Operating loss		(5,009)		(6,603)		(15,459)		(13,736)	
Interest income		22		26		49		104	
Loss before benefit from income taxes		(4,987)		(6,577)		(15,410)		(13,632)	
Benefit from income taxes		200		32		250		59	
Net loss	\$	(4,787)	\$	(6,545)	\$	(15,160)	\$	(13,573)	
Net loss per share:									
Basic and Diluted	\$	(0.19)	\$	(0.29)	\$	(0.64)	\$	(0.67)	
Weighted average shares:									
Basic and Diluted	2	5,545,164	22,	713,040	23	3,737,443	2	0,351,005	

#### **INVESTOR CONTACT:**

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#### **MEDIA CONTACT:**

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